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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,320	08/18/2006	John W. Hadden	3115.00083	6669

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EXAMINER

WEN, SHARON X

ART UNIT PAPER NUMBER

1644

MAIL DATE DELIVERY MODE

09/04/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/567,320

Applicant(s)

HADDEN, JOHN W.

Examiner

Sharon Wen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The art unit location of the examiner of this application in the PTO has changed. To aid in the correlating any papers for this application, all further correspondence regarding this application should be directed to Sharon Wen, Group Art Unit 1644, Technology Center 1600.

2. Applicants election with traverse of Group I, claims 1-11, 14-17, and 21-29 in the Response to Election / Restriction filed on 06/14/2007 is acknowledged.

Upon further consideration, the previous Restriction Requirement mailed 04/06/2007 has been vacated and a new Restriction Requirement is set forth in this Office Action.

Claims 1-32 are pending and currently under restriction requirement.

The examiner apologizes for any inconvenience to Applicant in this matter.

Election/Restriction

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-16 and 24-29 drawn to a method of immunotherapy to treat cancer by administering an effective amount of natural cytokine mixture (NCM) and combination thereof.

Group II, claim(s) 17 and 30-32, drawn to a composition comprising cyclophosphamide (CY), indomethacin (INDO) and/or NCM.

Group III, claim(s) 18, drawn to an anti-metastatic treatment method comprising the steps of promoting differentiation and maturation of immature dendritic cells in a lymph node.

Group IV, claim(s) 19-20, drawn to an anti-metastatic method by unblocking immunization at a lymph node.

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Group V, claim(s) 21, drawn to a method of using a natural cytokine mixture as a diagnostic skin test for predicting treatment outcome.

Group VI, claim(s) 22, drawn to a method of pre-treatment of dendritic cells (DC) by applying an effective amount of CY and INDO in combination with an NCM.

Group VII, claim(s) 23, drawn to A method of treating monocyte defects characterized by sinus histiocytosis or a negative NCM skin test by applying an effective amount of CY and INDO in combination with an NCM.

Given the differences in the preambles between the Groups I and III-VII and the absence of essential ingredients in Groups III and IV, the claimed methods have been set forth as Groups, as indicated above.

Applicant is invited to distinguish between Group III (claims 18) and Group IV (claims 19-20). If the method steps and endpoints are the same or nearly the same as they read on immunotherapy of cancer or the development of metastasis, then Groups III and IV will be rejoined.

4. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: PCT Rule 13.2 defines "special technical features" as "those technical features that defines a contribution which each of the claimed inventions, considered as a who makes over the prior art."

The special technical feature in the present application is immunotherapy by administering an effective amount of NCM. Hadden (U.S. Patent 5,632,983) teaches a cancer immunotherapy treatment using a therapeutic NCM (a composition which contains 200-500 units of IL-2 (column 6)- a compound notoriously old and well known for the treatment of cancer). As such, the technical feature in the present application does not make a contribution over the teachings of Hadden. Thus, the unity of invention does not exist.

Species Election

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

6. This application contains claims directed to the following patentably distinct species of the claimed Groups, wherein the composition in the product claims or the composition in the method claims comprise

A) a cytokine or combinations thereof, **AND/OR**

B) cyclophosphamide, **AND/OR**

C) NSAID or combinations thereof.

If any one of Groups I-II and VI-VII is elected, Applicant is required to elect a particular **combination** of (A) and/or (B) and/or (C). If appropriate, this species election requirement also applies to Groups III and IV.

If Groups V is elected, Applicant is required to elect a particular combination of (A).

Applicant is required to elect a particular combination of (A) **AND/OR** (B) **AND/OR** (C), which is consistent with the instant claims and the written description of the instant application as filed.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the only feature uniting the inventions is the use of NCM for immunotherapy; this feature lacks novelty, see teaching of Hadden. Therefore no special technical feature unites the inventions.

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Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. If Group I is elected, Applicant is required to elect a specific administering step as recited in claims 4-7 (e.g., "unilaterally administering").

In addition, if Group I elected, Applicant is required to elect a specific administering step as recited in claims 8-9 (e.g. administering prior to surgery or radiotherapy OR administering during recurrence of tumors)

Furthermore, if Group I is elected, Applicant is required to elect a specific tumor antigen as recited in claim 20 (e.g., endogenous OR exogenous).

Lastly, if Group I is elected, Applicant is required to elect a specific cancer as disclosed in the instant specification on pages 20, 29, 30, 33 and 34(e.g. cervical cancer)

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the only feature uniting the inventions is the use of NCM for immunotherapy; this feature lacks novelty, see teaching of Hadden. Therefore no special technical feature unites the inventions

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the only feature uniting the inventions is the use of NCM for immunotherapy; this feature lacks novelty, see teaching of Hadden. Therefore no special technical feature unites the inventions.

Notice of Possible Rejoinder

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

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Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Wen whose telephone number is (571) 270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571)272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Wen, Ph.D.

Patent Examiner

August 28, 2007


PHILLIP GAMBEL, PH.D. JD
PRIMARY EXAMINER
JC 1600
8/28/07